REMARKS/ARGUMENTS

Reconsideration of this application is respectfully requested.

The rejection of claims 22-26, 28-31, 36, 38-40 and 42 under 35 U.S.C. §103 as allegedly being made "obvious" based on Yamazaki '825 in view of John '335 is respectfully traversed.

The claims have been amended, now reciting the word "sensory" to indicate that the stimulus applied is a sensory stimulus. The claims also now recite that a plurality of electrodes are provided on the body and a current is passed between selected areas of the surface of the body by passing a current between at least one pair of the electrodes, the current being provided by a current source external to the body. The claims also now clarify that the measurement period is initiated after a predetermined delay following occurrence of the stimulus – and while injected current still flows.

Claim 22 is directed to a method for monitoring the response of a nervous system of a body to sensory stimuli. The method comprises providing a plurality of electrodes on a surface of the body and passing current between selected areas of the surface of the body by passing current between at least one pair of electrodes of said set of electrodes, said current being provided by a current source external to the body. A set of voltage measurements between selected ones of the electrodes is collected while the injected current is flowing. The set of voltage measurements is collected over a predetermined measurement period, the predetermined measurement period being

initiated after a predetermined delay following occurrence of the stimulus and the collected voltage measurements are compared with reference measurements to determine normal or abnormal response of the nervous system.

Different parts of the brain are active at different times after occurrence of stimuli. By beginning the predetermined measurement period after a predetermined delay following occurrence of the stimuli, the obtained data is indicative of brain activity at a particular time after occurrence of the stimuli. The inventors have realized that by obtaining data indicating brain activity at a particular time delay after the stimuli, this data can be analyzed to determine which parts of the brain are active at a particular time after a stimulus occurs. The inventors have realized that this enables determination of whether a particular part of the brain is responsive to the stimuli.

Yamazaki is directed to an evoked potential measuring apparatus in which an evoked potential can be measured (see Abstract). Yamazaki is directed to measuring an evoked potential, that is, an electrical potential evoked by the stimulus and is recorded using, for example, EEG. Such evoked potentials are low amplitude, passive signals.

The additional feature of claim 22, of a current being provided by a current source external to the body makes clear that a current is applied to the body from an external source and is not generated by the body itself. This is quite different from Yamazaki's arrangement. At 6:55 to 7:10, Yamazaki describes applying electrodes to

measure evoked potential, but there is nothing to teach or suggest that current is passed between selected regions of the surface of the body from an external source. Indeed, the Examiner's argument that current is passed appears to be based upon a current which is caused by the evoked potential, not any current provided from an external source. Indeed, it is noted that the Examiner explicitly accepts (office action, page 14, line 20) in relation to claim 32 that Yamazaki does not teach passing a current between selected areas of the body.

The Examiner asserts that Yamazaki discloses at 6:45-50 and 7:20-25 the feature of claim 22 that the predetermined measurement period is initiated a predetermined time after application of the stimulus. While applicants respectfully traverse the Examiner's assertion, claim 22 has been clarified to indicate that the predetermined measurement period is initiated after a predetermined delay following occurrence of the sensory stimulus.

At 6:45-46 and 6:49-50, Yamazaki describes a period of time for which the brain potential is to be measured, and a period of time for which the physiological measure is to be measured, respectively. At 7:20-25, with reference to Fig. 5, Yamazaki describes that each time light is emitted from the flash apparatus, a signal of the brain potential is recorded for a preset time. It can be seen from Fig. 5 of Yamazaki that brain potential data is measured continuously, indicated by the continuous line marked "brain potential data."

Indeed, Yamazaki discloses constant measurement of brain potential while a plurality of stimuli is applied to a patient and there is no delay between measurement and application of the stimuli. This is further demonstrated by Yamazaki's Figs. 3 and 4 which show brain potential data being measured continuously from before the stimuli occurs. It is clear, therefore, that there is nothing in Yamazaki to teach or suggest that the predetermined measurement period is initiated after a predetermined delay following occurrence of the stimuli.

The Examiner argues that it would have been obvious to a person of ordinary skill in the art to modify Yamazaki to include features from John and thus to arrive at applicants' claim 22. However, even if this combination were made, *arguendo*, there is nothing in Yamazaki or John to teach or suggest a current being provided by a current source external to the body or that a predetermined measurement period is initiated after a predetermined delay following occurrence of the stimuli.

As indicated above, the inventors have realized that by beginning the predetermined measurement period a predetermined time after application of the stimuli, the obtained data can be analyzed to determine which parts of the brain are active at different times after a stimulus occurs and enabling them to determine if a particular part of the brain is responsive to the stimuli.

The above-noted distinction from Yamazaki/John with respect to independent claim 22 also applies to independent claims 36, 38 and 42. Given such fundamental

deficiencies with respect to these aspects of the independent claims, it is not believed necessary at this time to discuss additional deficiencies of this allegedly "obvious" combination of references with respect to other aspects of the rejected claims. Suffice it to note that, as a matter of law, even a *prima facie* case obviousness must be supported by cited prior art that teaches or suggests every feature of a rejected claim.

The rejection of claim 27 under 35 U.S.C. §103 as allegedly being made "obvious" based on Yamazaki/John in further view of Vauhkonen is also respectfully traversed.

Fundamental deficiencies of Yamazaki/John have already been noted with respect to parent claim 22. Vauhkonen does not supply those deficiencies. Accordingly, it is not necessary at this time to discuss additional deficiencies of this allegedly "obvious" three-way combination of references with respect to the additional limitations of claim 27.

The rejection of claims 32, 34, 35 and 37 under 35 U.S.C. §103 as allegedly being made "obvious" based on Yamazaki in view of Polydorides is also respectfully traversed.

Claim 32 is directed to a method for monitoring the response of a nervous system of a body to sensory stimuli. The method of claim 32 substantially corresponds to the method of claim 22 with the additional feature that the predetermined delay is

selected on the basis of a neurological model of the nervous system and the predetermined part of the nervous system for which a response is monitored.

From neurological models, it is possible to determine *a priori* which parts of the brain should be active at set times after occurrence of stimuli. The inventors have realized that by selecting a delay based upon neurological model of the nervous system and collecting voltage measurements after the selected delay, it is possible to better identify the response of the expected part of the nervous system to the stimuli.

The Examiner argues that Yamazaki's system has a built-in delay. As noted above, this argument is respectfully traversed. The Examiner further argues that Yamazaki's system is designed to monitor a response from a human physiological model and, therefore, the built-in delay is designed on the basis of the human neurological model to monitor response. However, there is no disclosure in Yamazaki of a delay that is based upon a neurological model of the nervous system. Yamazaki does not disclose a delay and even if there is some delay inherent in Yamazaki's system, there is nothing in Yamazaki to teach or suggest that this delay is in any way selected on the basis of a neurological model of the nervous system.

Polydorides does teach a current being provided by a current source external to the body. The Examiner appears to indicate that since electrodes for providing a current source are placed where the targeted response to stimuli is expected to occur,

this discloses the feature of selecting a predetermined delay on the basis of a neurological model of the nervous system. This is not understood.

While it is reasonable to infer that the location of electrodes for measuring a current in Polydorides is selected on the basis of a model of the nervous system, that is, the electrodes will be located near the part of the nervous system that is being tested, this cannot be said to teach or suggest a predetermined delay on the basis of a neurological model of the nervous system, the predetermined delay indicating a delay following occurrence of applied sensory stimuli. It is clear, therefore, that neither Yamazaki nor Polydorides contains the feature of a predetermined delay selected on the basis of a neurological model of the nervous system.

The above-noted distinctions also apply to independent claim 37. In view of the fundamental deficiencies of Yamazaki/Polydorides with respect to independent claims 32 and 37 as already discussed above, it is not necessary at time to discuss additional deficiencies of this allegedly "obvious" combination of references for reasons noted above.

The rejection of claim 33 under 35 U.S.C. §103 as allegedly being made "obvious" based on Yamazaki/Polydorides in further view of John '335 is also respectfully traversed.

Fundamental deficiencies of Yamazaki/Polydorides have already been noted above with respect to parent claim 32.

The rejection of claim 41 under 35 U.S.C. §103 as allegedly being made "obvious" based on Wells '889 in view of Yamazaki '825 is also respectfully traversed.

Claim 41 is directed to a method for monitoring the response of a nervous system of a body to sensory stimuli. The method of claim 41 substantially corresponds to the method of claim 22 with the additional feature that user input indicating a time delay is received, and a predetermined delay is determined by the user input.

As set out above, Yamazaki does not teach the features of a current being provided by a current source external to the body and a predetermined measurement period initiated after a predetermined delay following occurrence of the stimuli. These features are also not taught by Wells.

Wells teaches electrical stimulation of a nerve bundle by surface electrodes (see, for example, paragraph [0003]. The electrical stimulation is then stopped and compound muscle action potentials are recorded from the stimulated nerve (paragraph [0003]). The method of Wells requires that a current is passed to stimulate a nerve and then the current is stopped to allow measurement of the current at a later point in the nerve. Wells is generally directed to the elimination of detected artifacts caused by the electrical stimuli that is applied. Wells indicates at paragraph [0004] that large artifacts

due to the electrical stimuli often appear in surface evoked potential traces, which it is desirable to eliminate.

As clarified in amended claim 41, and indeed all other independent claims, the stimuli in the present application is sensory stimuli and not electrical stimuli as is applied in Wells. Auditory and visual stimuli are provided as examples of sensory stimuli in the specification. A sensory stimulus causes the nervous system to function and its conductivity to change in the areas responsive to the sensory stimuli. For example, when the part of the nervous system that is measured is the brain, a particular part of the brain that relates to the nervous system sensory stimuli functions, causing a conductivity change within the particular part of the brain. The conductivity change of the nervous system is an intrinsic property of the nervous system and is in no way related to the applied electrical current of claim 41, which simply measures the conductivity change.

In claim 41, and in the invention of each of the claims of the present application, the electrical current that is passed while a set of voltage measurements is collected is a measuring current and not a stimulus. That is, the current and stimulus of claim 41 are entirely independent of one another. The stimulus causes the nervous system to function, while the current is simply a measuring current. The electrical current of Wells is applied and then stopped because the electrical stimulus of Wells causes artifacts and, if the current is not stopped, these artifacts would distort the measurements of the

desired action potential measurements. Indeed, Wells is concerned with the elimination of such artifacts which simply cannot occur in the invention of claim 41 because of the very different nature of the stimuli. It is clear, therefore, that there is no collecting a set of voltage measurements while the current is passed in Wells, and indeed Wells is directed to a quite different method than the present invention.

The Examiner is thanked for including a "response to arguments" section bridging pages 20-21 of the final office action. However, as should be clear from the above, the applicants respectfully continue to disagree with the Examiner.

In particular, Yamazaki only measures an evoked voltage and does not appear to apply an injected voltage/current into the subject at all. Accordingly, even prior to the above amendment, the applicants' claims required active current injections (i.e., while current is passed) and thus are clearly distinguished from Yamazaki's measurement of evoked voltage/current across electrodes applied to a subject.

Furthermore, the fact that Yamazaki does not wait to begin recording measurements has already been addressed above and is self-evident from the Yamazaki figures accompanying the specification text.

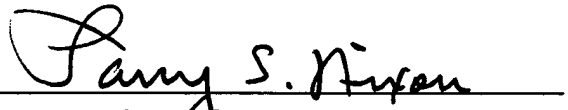
The Examiner's attention is also drawn to new independent claim 43 which is more particularly directed towards waiting an initial time delay after application of a predetermined sensory stimulus to inject electrical current through a pair of electrodes

affixed to the subject's head for a first time period, during which first time period, sequential measurements of electrical voltages appearing across further pairs of electrodes also affixed to the subject's head are made. Claim 43 also recites subsequent current injection/measurement time periods and repetitions of the entire procedure for different initial time delays so as to derive a time sequence of images revealing nervous system responses to the predetermined sensory stimuli in different parts of the brain. There is clearly no possible teaching or suggestion of such in any of the cited references.

Accordingly, this entire application is now believed to be in condition for allowance, and a formal notice to that effect is earnestly solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 

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